indicated as primary (n = 5) or secondary (n = 22; of which 4 are secondary and/or exploratory) or both (n = 12).The majority of PRO statements are characterized as sign and symptom measures followed by HRQOL measures. Within FDA, 5 required PRO and 8 suggest use of PRO. The majority of PRO statements are characterized as sign and symptom measures, followed by measures of function/feeling. **CONCLUSIONS:** PRO data in many disease areas are viewed by regulatory agencies as supportive evidence of the primary endpoint. PRO data are essential in the support of product submissions to regulatory stakeholders, especially within EMEA.

PMC22

THE IMPACT OF A HOST COUNTRY'S CULTURE ON IMMIGRANT LANGUAGE

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OBJECTIVES: To facilitate international comparison of data, PRO translations must be conceptually equivalent to the original and culturally relevant to the target country. To assess the relevance of conducting a multi-step process on a PRO translation with the aim of using it on an immigrant population speaking that language in a different country, we investigated the presence and nature of differences between the 2 language versions thus obtained. **METHODS:** Three translations were compared before and after adaptation to the context of a host country: 1) the Turkish and German Turkish version of the *Diabetes Treatment Satisfaction Questionnaire (DTSQ);* 2) the Indian Gujarati and UK Gujarati version of the *Subject Self Report on Symptoms Worksheet (SSRSW);* and 3) the Chinese Mandarin and US Mandarin version of the *National Eye Institute Visual Functioning Questionnaire (NEI-VFQ-25)*. **RESULTS:** Six of the eight items in the Turkish DTSQ were modified following cognitive debriefing with Turkish speakers in Germany. The Turkish population in Germany tends to use more old-fashioned wording which doesn't reflect the original language's recent evolution. All four items in the Gujarati SSRSW needed changing when adapting it to a UK context. Some initially translated wording was reverted back to English, or substituted with transliterated English terms. In the Mandarin NEI-VFQ-25, out of 29 items, 11 were modified when adapting it for the USA. The language used in the initial translation was considered too basic for the target population in the USA, which tends to have a higher level of education. **CONCLUSIONS:** Immigrant language is affected by the host country's culture and language, and/or by separation from the mother country, and is no longer fully comparable with the language in the country of origin. Adaptation and cognitive debriefing on immigrant populations in target countries is advisable to establish culturally relevant translations.

PMC23

A UNIVERSAL SCORING SYSTEM FOR EQ-5D : A VASTLY SIMPLER SOLUTION

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OBJECTIVES: Country-specific social preference sets have been estimated to support the use of EQ-5D in computing QALYs for cost-utility analysis. However these value sets have limited applicability in non-economic applications since a) they incorporate the state "dead" which is irrelevant in many therapeutic settings, and(b) they are based on hypothetical preferences from 3rd parties who may not have any experience of specific EQ-5D health states. This paper reports on the construction of a scoring system for EQ-5D based on self-rated VAS values generated by individuals with current experience of those states. **METHODS:** EQ-5D data from several different UK sources were pooled yielding a total of 23,679 useable observations. The health state defined by each respondent's self-rated problem level on the 5 EQ-5D dimensions was determined, yielding a total of 139 unique EQ-5D health states. The mean VAS rating was computed for each of these states. 0/1 dummy variables were defined for each of the EQ-5D dimensions and an OLS regression analysis was performed with the mean self-rated VAS rating as the dependent variable. **RESULTS:** The model fitted the mean VAS ratings data very well ($r^2 = 0.985$) when forced through the origin. All decrements within dimension were monotonic and internally consistent. Residuals were 5 points or lower when observed and estimated values were compared. Estimated values for all EQ-5D health states were computed so that full health (11111) has a value of 100 and worst possible health (33333) has a value of 0. **CONCLUSIONS:** This methodology contrasts markedly with the more complex requirements of utility estimation and produces a weighting system that can be used to meaningfully report health status. It has applicability as a performance measurement tool with real-world interpretability. If corresponding data from other countries were included then a single global scoring system for EQ-5D could be established.

PMC24

THE EFFECT OF FRAMING ON PREFERENCES FOR MAXIMIZING QALYS

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OBJECTIVES: To test whether social preferences for allocating health resources are affected by the framing of questions **METHODS:** 162 students from the University of Southern California were asked four questions. Each question asked participants to select one of two possible treatments with each treatment resulting in a different distribution of outcomes for the treated population. After treatment, patients could have one of three outcomes: "Good Health", "Poor Health", or "Death." The first medication listed always had 19 fewer people in "Good Health", 23 more people in "Poor Health" and 4 fewer people in the "Death" state relative to the second medication listed. The only aspect that varied between questions was the number of patients unaffected by treatment choice. Two questions had a "standard frame", indicative of commonly asked questions in the equity literature. The remaining two questions had a "sure thing" frame, in which common outcomes between the two treatments were made apparent. Frame order was randomized for each of the participants. A key qualitative principle behind QALY maximization is that those individuals unaffected by a policy choice should not influence the policy choice. Violations of this principle were measured for each of the frames. **RESULTS:** The proportion of violations of QALY maximization (indicated by switched preference) in the "standard" frame was 0.31 (56/183); while in the "sure-thing" frame, the proportion was 0.08 (15/183). The difference between groups was statistically significant ($p < 0.001$) **CONCLUSIONS:** The most common way of asking for preferences for equality tends to foster aversion to inequality, which does not support QALY maximization. In contrast, a frame that separates common outcomes between choices may occasion preferences that maximize QALYs. These results have implications for measurement techniques such as the person tradeoff which assumes framing has no effect on preferences for health allocation.

PMC25

PATIENT PREFERENCES FOR ADHERENCE TOOLS ACROSS 10 MEDICAL CONDITIONS

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OBJECTIVES: Recognizing that medication non-adherence is a significant cause of suboptimal health outcomes, the objective of this study was to obtain patient feedback on communication with providers and preferences for various adherence tools. **METHODS:** Online cross-sectional survey of patients with: asthma/COPD, allergies, bipolar disease, cardiovascular disease, depression, diabetes, multiple sclerosis, osteoporosis, pain syndromes, and rheumatoid arthritis. Patients completed close-ended questions about the amount of information they received from health care providers; the usefulness of various adherence tools in managing their condition; and the impact of additional disease/product information. Patient ratings of each adherence tool were scored on a scale ranging from 0 ("not at all valuable") to 3 ("very valuable"). Paired t-test was used to compare the preference for explicit adherence reminders (medication reminders via email, telephone and SMS text) versus each of the other adherence tools. The association of patient preferences for each tool with age was evaluated using Pearson correlation coefficients and using one-way analysis of variance (ANOVA) for associations with medical conditions, gender, education, family income and health insurance source. **RESULTS:** A total of 642 patients completed the survey. Forty percent reported receiving inadequate information from their physician (range: 22% for rheumatoid arthritis to 54% for cardiovascular disease). Across medical conditions groups, patients preferred adherence tools that conveyed information about medication dosing, safety, and drug interactions. Explicit adherence reminders were uniformly deemed least valuable compared to other adherence tools (all p-values < 0.0001 based on paired t-tests). There were some differences observed in preferences for adherence tools across condition, gender, and age; no significant associations were found between patient preferences and education level, family income, or source of health insurance. **CONCLUSIONS:** Patients often receive inadequate information about their medications and conditions. Medication adherence tools that educate patients may simultaneously address their desire for more information and reinforce adherence.

PMC26

EVALUATING TREATMENT SATISFACTION ENDPOINT EVIDENCE FOR EMEA REGULATORY APPROVALS

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OBJECTIVES: To document the extent to which treatment satisfaction evidence is provided in support of EMEA regulatory approvals and to evaluate the quality of evidence provided in support of treatment satisfaction claims.**METHODS:** A review of EMEA published reports for all drugs approved since a centralised process was established in 1995 was undertaken: specifically the Scientific Discussion/Public Assessment Reports were reviewed for evaluations of patient-reported treatment satisfaction. The wording and types of PROs contained within approved product labels were examined in order to establish the nature and extent of previous successful claims for treatment satisfaction.**RESULTS:** A total of 508 currently authorised medicinal product approvals were reviewed, 26 made reference to 'satisfaction' or 'satisfied' but 9 were excluded for not focusing on patient-reported treatment satisfaction thus 17 medicinal products were identified as having a direct reference to evaluating patient-reported treatment satisfaction. These 17 approvals ranged from July 1998 to July 2008, and were distributed across a broad range of pharmaco-therapeutic groups with a cluster of approvals for 'insulin analogues for injection, long lasting' (n = 4): 10/17 approvals provided limited reference to the way in which treatment satisfaction was evaluated e.g. reference to a total satisfaction score without any further details, 2/17 measured treatment satisfaction using a VAS; 5/17 referenced a specific treatment satisfaction measure. 5/17 provided treatment satisfaction of results, yet only two of these gave any details on the way in which treatment satisfaction was measured.